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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,383	01/14/2002	Louis Michael Crowe	660057-2010	5507

20999 7590 12/20/2006
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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/047,383	CROWE ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-136* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 15-29, 42-44, 56-59, 67-76, 81-95, 108-110, 122, 123, 133-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11-14,30-41,45-55,58-66,77-80,96-107,111-121 and 124-132.

DETAILED ACTION

Election/Restrictions

Claims 11-14, 30-41, 45-55, 58-66, 77-80, 96-107, 111-121, and 124-132 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 15-29, 67-76, 81-95, 108-110, 122, 123 and 133-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original disclosure is the feedback mechanism/monitor "that maintains the predetermined cardiac output by" controlling the signal generator based upon the cardiovascular response (and similar method steps), in combination with the other elements/steps in the claim. The original disclosure on pages 27-32 describes the use of a monitor or feedback mechanism, but not "maintaining" a "predetermined cardiac output" based upon the "cardiovascular response". This rejection is related to new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 15-24, 26-29, and 42-44, 56, 57, 135, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al (WO 00/41764). Minogue states that his device is used to stimulate/contract the muscles (abstract and throughout the specification), specifically the abs and transversalis and oblique muscles (page 24) and different muscles, such as the leg and back muscles (page 32), and uses electrodes sized from 80 to 120 mm by 50 to 150 mm (page 24) and delivers pulses using parameters of 50-1000 microseconds pulse duration, 1-200 Hz, and 0-100 mA (page 25) and pulses where the amplitudes are different (figure 18) and therefore is capable of meeting the functional use recitations in the claims of "inducing vibrations" in the muscles and generating a cardiovascular response greater than 50-70% or increase the subject's calorie consumption to at least about three times its resting metabolic rate

since Minogue uses the exact same pulse parameters and electrode sizes as the applicant to cause the muscles to contract/vibrate/shake. Also, since the pulses are delivered through the same sized electrodes and contain the same pulse parameters, the charge delivered by the Minogue will be the same and meet the claimed charge limitations.

But Minogue does not disclose the monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor or to maintain the response at the set cardiac output. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method of stimulation as taught by Minogue, with a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor and to maintain the response at a set output since it was known in the art that stimulation systems and methods use a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor and to maintain the response at a set output to provide feedback to the signal generator to allow the stimulation to be applied within physiological limits and at a safe level to the patient so the patient does not overexert himself or go outside of the physiological limits and to allow the physician to tailor the response to within defined limits most beneficial to the patient.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al. Minogue states on page 32 that electrodes can be used on different muscles such as leg muscles and discloses the electrode sizes can be varied on page 24, but does not disclose the length being 190 mm. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the electrode size in the muscle stimulation system as taught by Minougue, with the length of the electrode being 190 mm since it was known in the art that muscle stimulation systems provide longer electrodes, such as being of the length of at least 190 mm, to efficiently stimulate the longer muscles to cause them to contract without causing pain or burning due to the electrical pulse. In addition, Minogue provides a clear suggestion that the electrodes can be modified to vary electrodes to fit the patient and muscle being stimulated. The determination of the most appropriate electrode size by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Response to Arguments

Applicant's arguments filed 9/21/06 have been fully considered but they are not persuasive. Minogue uses the same pulse parameters and electrode sizes as in the applicants claims. Although Minogue may not use the term "vibrations", "shivering", "cardiovascular training" or "contractions occurring at 3-12 Hz", Minogue does (inherently and/or is capable of) perform these functions since he uses the same pulse parameters and electrodes as stated in the applicant's specification and/or claims. The argument that apparatus claims 26-29 were not rejected with art is not correct since the previous office action of 4/17/06 rejected those claims with Minogue. The argument that the 103 rejections based on common knowledge in the art are not proper and are not of notorious character is not persuasive since the examiner previously provided several references showing this was well known in the art (and discussed this in the last office action).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
12/8/6

GRE
12/08/06